TESTIMONY OF

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on

Protecting Patients from Defective Medical Devices

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My name is Tom McGarity. I hold the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas School of Law, where I teach courses in Torts and Environmental Law. I am also a member of the Board and immediate past president of the Center for Progressive Reform. I have recently published a book entitled *The Preemption War: When Federal Bureaucracies Trump Local Juries*, in which I explore in some detail the issues that are before your committee today. I am very pleased to be here to testify on the topic of federal preemption of state common law claims and on the "savings clause" in S.B. 540 that, as I understand it, is intended to exempt state common law claims from the express preemption clause in the Medical Device Amendments to the Food, Drug and Cosmetics Act. Please note that I am expressing my own views and not necessarily those of the University of Texas or the Center for Progressive Reform.

The Medical Device Amendments and the *Riegel* Opinion.

Although the Supreme Court has frequently invoked a "presumption against preemption" in "areas of traditional state regulation,"[1] it has expanded the range of federal programs that preempt state common law during the past 20 years.[2] This process began with the Court's 1992 holding, in *Cipollone v. Liggett Group, Inc.*, that the word "requirement" in an express preemption clause could include state common law claims.[3] This much-criticized opinion invited defendants to raise the federal preemption defense in every case in which the relevant statute used the word "requirement" or similar words that could broadly be interpreted to include common law duties.

Medical devices were not regulated at the federal level until the Dalkon Shield tragedy in the early 1970s motivated Congress to enact the 1976 Medical Device Amendments to the Food, Drug and Cosmetics Act.[4] The unambiguous purpose of the statute was to protect patients from future Dalkon Shield disasters by ensuring that dangerous devices did not enter the marketplace in the first place.[5] To accomplish this purpose, the statute created a comprehensive regulatory regime under which medical devices in the most dangerous of three categories may not be put on the market until the manufacturer has

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[1] Bates v. Dow Agrosciences, LLC, 544 U.S. 431, 449 (2005) (quoting New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995)); Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707, 716 (1985).

[2] Thomas O. McGarity, The Preemption War, ch.4 (2008); Robert L. Rabin, Federalism and the Tort System, 50 Rutgers L. Rev. 1, 27 (1997).

[3] Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992).

[4] Medtronic, Inc. v. Lohr, 518 U.S. 470, 476 (1996); Richard B. Sobol, Bending the Law: The Story of the Dalkon Shield Bankruptcy (1991).

[5] Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

demonstrated to FDA that there is a "reasonable assurance" that they were both safe and effective.[6]

The Medical Device Amendments contain an express preemption clause that uses the magic word "requirement."[7] As a historical matter, the express preemption clause was added to the statute because several states, including California, were considering or enacting legislation to fill the void left by the absence of a federal regulatory regime. The statute lacks a "savings clause" exempting state common law claims from the ambit of the preemption clause. This is no doubt attributable to the fact that prior to the *Cipollone* case, few if any lawyers imagined that the word "requirement" included state common law claims.

In the 1996 case of *Medtronic, Inc. v. Lohr*,[8] the Court held that that the Medical Device Amendments preempted some, but not all common law claims directed toward medical devices that FDA had approved using the very abbreviated process that the statute provides for devices that are "substantially equivalent" to devices in existence in 1976.

Twelve years later, in *Riegel v. Medtronics, Inc*.,[9] the Court took up the issue of devices that had undergone the full FDA approval process. The Court there held that the word "requirement" in the statute's express preemption clause encompassed Riegel's common law claims. In broad dicta that defendants are relying on in currently pending cases, the Court added that "[a]bsent other indication, reference to a State's 'requirements' includes its common-law duties."[10] Noting that during the full approval process "the FDA requires a device . . . to be made with almost no deviations from the specifications in its approval application,"[11] the Court explained that "State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect."[12]

While the court's reasoning is certainly open to criticism, the fundamental flaw, in my view, dates back to the *Cipollone* opinion. It is therefore highly unlikely that the Court will revisit either decision in the foreseeable future. I take the position in my book *The Preemption War* that the best way to reverse this trend toward federal agency preemption

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[6] 21 U.S.C. § 360e(d)(2); Richard C. Ausness, "After You, My Dear Alphonse!": Should the Courts Defer to the FDA's New Interpretation of § 360k(A) of the Medical Device Amendments, 80 Tulane L. Rev. 727 (2006), at 731-33.

[7] 21 U.S.C. § 360k(a).

[8] Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

[9] Riegel v. Medtronics, Inc. 128 S.Ct. 999 (2008).

[10] 128 S.Ct., at 1008.

[11] 128 S.Ct., at 1007.

[12] 128 S.Ct., at 1008. To the extent that the plaintiff's claim was based on a company's violation of FDA's regulations, however, there was no variance between the duty imposed by the federal government and that imposed by the common law. Therefore, such claims were not preempted.

of state common law claims is for Congress to revisit the relevant statutes on a case-by-case basis.[13] That is exactly what S. 540 does, and I commend your committee for taking up this important issue.

The Corrective Justice and Deterrence Functions of the Common Law.

"Corrective justice" is a bedrock principle of civil society that dates back at least as far as Aristotle. Broadly stated, corrective justice requires that the state correct unjust changes in wealth that result from interactions among the members of a polity, usually by way of a financial arrangement. The compensation function of the common law provides corrective justice by requiring manufacturers of defectively designed or manufactured products to compensate innocent persons who have been injured by such products. I can think of no better example of corrective justice than the principle that the manufacturer of a defective medical device must compensate innocent patients who have been injured by the defective aspects of that device.

The accountability afforded by the civil justice system also provides a powerful incentive to companies to avoid causing harm in the first place.[14] To the extent that the anticipated compensatory and punitive damage awards imposed by the civil justice system are greater than the cost of avoiding the harm, a rational company will take protective action to prevent causing damage in the future.[15] In this way, tort law provides a valuable backstop to the regulatory system by sending a message to potential defendants to collect data on the harm-producing potential of their products and activities and to take action to prevent future harm.[16] Indeed, litigation may be more effective in removing risky products from the market than regulatory controls.[17]

The deterrence function of state tort law is especially relevant to medical devices for two reasons. First, the device manufacturers that conduct the clinical trials and continually receive reports on their products will generally have access to more information on the risks posed by their products than doctors, patients or even FDA. Second, device manufacturers are in a far better position than doctors, patients or FDA to improve the safety of their products both before and after they enter the marketplace. The manufacturers' incentive not to violate its common law duty to market non-defective medical devices therefore reinforces the protective policies underlying the Medical Device Amendments.

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[13] Thomas O. McGarity, The Preemption War ch.10 (2008).

[14] See Thomas O. McGarity, The Preemption War 32-33 (2008).

[15] Dan B. Dobbs, The Law of Torts (2000), at 19-21; Gary T. Schwartz, Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice, 75 Tex. L. Rev. 1801 (1997), at 1832.

[16] See Mary L. Lyndon, Tort Law and Technology, 12 Yale J. Reg. 137 (1995), at 143; Wendy Wagner, When All Else Fails: Regulating Risk Products Through Tort Litigation, 95 Georgetown L. J. 693 (2007), at 727.

[17] Alexandra B. Klass, Pesticides, Children's Health Policy, and Common Law Tort Claims, 7 Minnesota J. of Law, Science, & Technology 89 (2005), at 118.

The Consequences of Preemption.

Congress only very rarely speaks explicitly to state common law (as opposed to state statutes and regulations) in express preemption clauses. When it does, it invariably provides an alternative route to corrective justice by creating either a separate federal cause of action or an alternative administrative compensation regime.[18] Congress typically creates a national compensation regime because it concludes either that the common law of some states inadequately advances important public policies or that a national system with uniform rules is necessary to ensure the continued availability of valuable products and activities. An example of the former is the Federal Employees Liability Act, which was enacted in 1908 to replace regressive state common law doctrines that shielded railroads from liability with a more "enlightened" federal common law cause of action for workers of interstate common carriers.[19] An example of the latter is the National Childhood Vaccination Injury Act (NCVI Act) of 1986, which provides swift compensation for persons injured by vaccines, while at the same time ensuring that litigation risks do not hamper the country's supply of effective vaccines.[20]

When a court interprets an express preemption clause that mentions state "requirements" and does not include an alternative compensation regime to include state common law claims, it deprives victims of their right to compensation from the wrongdoers who injured them. There is no alternative compensation regime available in these cases to provide corrective justice. In the case of uninsured victims, their medical expenses are as often as not picked up by the states or the federal government. Furthermore, a finding that a products liability claim is preempted robs the common law of the "backup" role that it plays by way of providing an incentive to device manufacturers not to market defective products.

For these reasons, I believe that Congress should be very reluctant to deprive victims of corrective justice and to deprive federal agencies of the common law's "backstop" function behind the veil of express preemption clauses, and it should be very quick to correct the injustice that results when a court misinterprets an express preemption clause using the word "requirement" to eliminate victims' rights to corrective justice. That is why I believe that a statute like S. 540 should be on the congressional agenda in the wake of the *Riegel* opinion.

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[18] Timothy D. Lytton, The NRA, The Brady Campaign, & the Politics of Gun Litigation, in Timothy D. Lytton, ed., Suing the Gun Industry (Univ. of Michigan Press 2005), at 152, 174.

[19] 45 U.S.C. §§ 51-60. See Dan B. Dobbs, The Law of Torts (2000), at 40, 312; Robert L. Rabin, Federalism and the Tort System, 50 Rutgers L. Rev. 1 (1997), at 26.

[20] 42 U.S.C. § 300aa-11-15; Moss v. Merck & Co., 381 F.3d 501 (5th Cir. 2004), at 503. See generally Thomas F. Burke, Lawyers, Lawsuits, and Legal Rights (Berkeley, U. California Press 2002), at ch. 4.

Policy considerations.

Although much of the law of preemption derives from judicial opinions, it is important to recognize at the outset that the determination whether a federal regulatory regime should preempt state law is entirely within the discretion of Congress. How Congress exercises that discretion is ultimately a policy question that requires Congress to balance several important considerations, many of which I highlight in chapters 7-9 of *The Preemption War*. I have already alluded to the overarching policy of preserving the capacity of the common law to provide corrective justice. I will briefly summarize some other considerations below and explain why, in the case of medical devices, it is my view that a savings clause like that contained in S. 540 represents sound public policy.

Conflict Avoidance

The most powerful policy rationale for preempting any state law is the potential for conflict between that law and federal law. The Supreme Court has recognized that conflict comes in two varieties. First, two bodies of law may impose conflicting obligations on those who are subject to them. Thus, a state law that requires a person to take an action that violates a federal regulation presents a conflict that renders compliance with both impossible. Although common law injunctive relief could easily bring about such a direct conflict, a common law claim for damages would present such a direct and forceful conflict only in the difficult-to-imagine case in which a federal regulation prohibited a company from paying damages to an injured plaintiff. Nevertheless, it would usually be unfair to force a company to pay damages for violating a common law duty that directly conflicts with a federal regulatory requirement.

Second, the two bodies of law may be at cross purposes, as when compliance with state law would present an obstacle to achieving an important policy underlying a federal regulation. In my view, there is little risk that allowing victims of defective medical devices to seek corrective justice from manufacturers of defective devices will cause a conflict with an important federal policy. To the extent that the device fails to comply with federal requirements, allowing common law claims to proceed would simply reinforce the primary purpose of the Medical Device Amendments, which is to protect patients from poorly designed and manufactured medical devices, by providing an added incentive to manufacturers to be careful. There is some risk that common law actions could hinder a federal policy favoring the availability of medical technologies if the threat of liability caused companies to withdraw FDA-approved devices unnecessarily. The magnitude of that risk, however, depends upon the ability of FDA to address previously approved devices as new information related to risk and efficacy becomes available, a topic that I discuss below.

Institutional Competence

The primary advantage that regulatory agencies have over state common law is the expertise that they can bring to bear on the scientific and technical issues. Jurors can become confused or bored by complex presentations. On issues that turn on scientific or technical evidence, they may be more easily swayed than agency experts by emotion or irrelevant policy considerations. Yet the available empirical evidence suggests that juries are capable of comprehending complex scientific and technical issues quite objectively with the help of judge-screened experts.

Agencies also develop a policymaking expertise that gives them a clear advantage over courts in addressing major issues of national policy. That form of expertise is, however, less relevant to issues related to the risks of individual products that arise in products liability litigation regarding medical devices.

At the same time, agencies are far from omniscient. They are notoriously subject to "capture" by the very interests that they are charged with regulating. FDA is almost entirely dependent on information submitted by medical device manufacturers at the initial approval stage, and that information is easily manipulated by unscrupulous companies and their consultants.[21] Because the device approval process is cloaked in secrecy, agency reviewers do not have the benefit of skeptical outsiders from public interest and patient advocacy groups. FDA also lacks subpoena power to obtain internal company documents that can tell a very different story than the one the agency reviewers hear in their meetings with company officials.

Common law courts have institutional advantages over federal agencies that should also be weighed in the balance. Perhaps the strongest institutional advantage of common law litigation is its ability to force information from company files and tease it out of company employees in depositions. Courts are also better adapted than agencies to respond rapidly to developments in the real world as new information on the hazards of products and activities becomes available. Finally, courts are far less subject to capture, manipulation and political pressure than federal agencies.

Institutional Capacity

Resource-starved federal agencies like FDA do not have sufficient personnel to keep up with ongoing technological developments, and they are generally very reluctant to revisit previous decisions in light of new information. As a practical matter, the promise that they offer to bring both technical and policymaking expertise to bear on issues that are also frequently litigated in common law courts may be a hollow one. Yet the implicit assumption underlying federal preemption of common law claims is that the federal regulatory agencies are performing their jobs nearly perfectly. Otherwise, the common law still has a role to play in providing corrective justice to victims of defective products.

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[21] See Marcia Angell, The Truth About Drug Companies (2004); Jerome P. Kassirer, On the Take (2005); Thomas O. McGarity & Wendy A. Wagner, Bending Science (2008),

The Common Law Backstop

As discussed above, the common law provides a valuable "backstop" role when agencies fail to provide the degree of protection envisioned by their authorizing statutes. The threat of common law liability provides incentives for regulatees to take protective action when evolving practices and technologies create unanticipated gaps in the coverage of regulations and permit requirements that are difficult for agencies to fill on a short-term basis. It also provides a disincentive to engage in artful schemes to avoid the reach of regulatory requirements. Finally, by providing a procedural advantage to plaintiffs who can show that their harm was caused by violations of regulatory requirements, common law litigation can assist agency enforcers in their compliance assurance efforts.

Federalism

The states have historically played the dominant role in protecting consumers and other victims of harmful business practices and activities. In some important areas, like environmental protection, that dominance has been replaced by that of federal agencies administering the landmark legislation of the 1960s and 1970s. In other areas, like consumer protection generally, the states remain the dominant institutional actors. And state courts have traditionally been the dominant institutions for providing corrective justice to American citizens. Since "regulatory wisdom does not reside exclusively in federal agencies," the experiments with lawmaking that are constantly going on in the 50 states can benefit the nation as a whole.[22] Indeed, the combined resources of state courts and federal agencies can usually accomplish a great deal more than the efforts of either one operating alone.

"Overdeterrence"

Some scholars have argued that the deterrence function of common law in the context of multiple sovereignties can go too far and cause manufacturers to over-invest in safety and therefore under-invest in the development of useful products.[23] To the extent that the amount invested in safety exceeds the value of the damage caused discounted by the probability that damage will in fact occur, the argument goes, this "overdeterrence" is economically inefficient and could delay the development of important medical technologies.

Given the strongly protective purpose of the Medical Device Amendments of 1976, I think the burden should be on the medical device industry to make that case with hard empirical evidence, and not vague allusions to a supposed "device lag." Although think

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[22] Richard J. Pierce, Regulation, Deregulation, Federalism, and Administrative Law: Agency Power to Preempt State Regulation, 46 U. Pittsburgh L. Rev. 607 (1985), at 656 (regulatory wisdom quote); Nina A. Mendelson, *Chevron* and Preemption, 102 Mich. L. Rev. 737 (2004), at 767.

[23] See Richard A. Epstein, Overdose (2006).

tank reports and op-ed pages are filled with claims that the American civil justice system is depriving citizens of useful technologies, I have seen very little hard empirical support for such claims in the context of either drugs or medical devices. In my view, the deterrence function of state common law performs outweighs any speculative "overdeterrence" that might result from the possibility that device manufacturers may be called upon to compensate the victims of defective devices.

Conclusions.

The decision to preempt state law is uniquely within the power of Congress, and Congress has a responsibility to speak clearly to the issue of state common law when it enacts regulatory statutes that preempt state statutes, regulations, and other "requirements." Congress has spoken clearly in many important regulatory statutes through savings clauses articulating a congressional intent not to preempt state common law claims. Your committee has an opportunity to speak clearly to this issue in the increasingly important context of federally regulated medical devices. I would urge you to take advantage of that opportunity.